K043354

JAN 10 2005

## 510(k) Summary

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| **Submitted By:** | Medical Data Electronics, Inc.<br>12601 Research Parkway<br>Orlando, FL 32826<br>(800) 331-3220<br>(407) 249-2022 (fax) |
| **Contact:** | Neil Battiste<br>Director of Regulatory Affairs |
| **Date of Preparation:** | December 3, 2004 |
| **Establishment Registration No:** | 1051786 |
| **Device Name:** | Vision Telepak™ Telemetry Transmitter |
| **Common/Classification Name:** | Monitor, Cardiac |
| **Device Classification:** | Class II |
| **Regulation Number:** | CFR 870.2300 and 870.2700 |
| **Classification Panel:** | Division of Cardiovascular |
| **Product Code:** | 74DRT and 74DQA |
| **Predicate Device:** | MTS Option for the Escort II Monitor, K970763 |

### Device Description:

The Vision Telepak Telemetry Transmitter unit is a portable, wireless, patient monitor intended to be used for monitoring the ECG and SpO2 vital signs of critically ill and pediatric patients. The Telepak unit is used in all areas of the hospital which utilize telemetry transmitters for ECG and/or SpO2 monitoring. The Telepak transmits vital sign information to an ESCORT Vision Central Station or an ESCORT Series bedside monitor. Both the central station and beside monitors were cleared under K970763.

### Intended Use:

The Vision Telepak Telemetry Transmitter is a portable monitor intended to be used for monitoring vital signs on critically ill adult and pediatric patients in the hospital environment.

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**Comparison to the Predicate Device:**

The Vision Telepak Telemetry Transmitter and the MTS Option for the Escort II Monitor are both portable monitors which are used to monitor ECG and SpO2. Both systems transmit vital sign information to either an ESCORT Vision Central Station or an ESCORT Series bedside monitor.

The systems differ in that the Telepak unit has been enhanced by reducing the size which makes the product easier to handle. In addition, the Telepak unit now requires 2 AA batteries instead of a 9v battery.

**Environmental and Non-Clinical Testing:**

Applicable environmental and non-clinical testing was performed per UL-2601-1 and EN 60601-1-2 as well as other applicable standards and procedures. The Vision Telepak Telemetry Transmitter passed all tests.

**Performance Testing:**

The study conducted to compare equivalency of the MTS Option for the Escort II Monitor 510(k) cleared device to the modified Vision Telepak Telemetry Transmitter met the performance requirements for accuracy and precision relative to the reference laboratory system. Equivalent performance in meeting user requirements was determined.

**Conclusion:**

The test results demonstrate the Vision Telepak Telemetry Transmitter is substantially equivalent to the MTS Option for the Escort II Monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2005

Invivo Research, Inc.
c/o Mr. Neil Battiste
Director of Regulatory Affairs
Medical Data Electronics
12601 Research Parkway
Orlando, FL 32826

Re: K043354
Trade Name: Vision Telepak™ Telemetry Transmitter
Regulation Number: 21 CFR 870.2300 and 21 CFR 870.2700
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm) and Oximeter
Regulatory Class: II (two)
Product Code: DRT and DQA
Dated: December 03, 2004
Received: December 06, 2004

Dear Mr. Battiste:

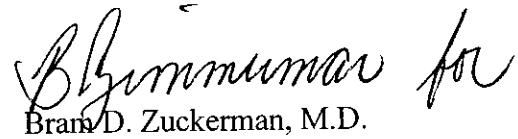
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K043354

Device Name: Vision Telepak™ Telemetry Transmitter

Indications for Use:

The Vision Telepak™ Telemetry Transmitter is portable monitor intended to be used for monitoring vital signs on critically ill adult and pediatric patients in the hospital environment.

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| Prescription Use X | AND/OR | Over-The-Counter Use _____ |
| (21 CFR 801 Subpart D) | | (Part 21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Runnimara

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043354